



Department of Public Health and Human Services

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Steve Bullock, Governor

Sheila Hogan, Director

Date: September 24, 2018
To: Vaccines for Children Providers
From: Montana Immunization Program
Re: Data Logger Policy Change Frequently Asked Questions

Below are answers to frequently asked questions about our data logger policy change effective October 31, 2018. Please direct additional questions to Lori Hutchinson at lhutchinson@mt.gov or 444-0277.

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1. What is changing after October 31, 2018?

- Providers will be responsible for their own data loggers and calibrations including one backup.
- Providers must [register data loggers](#) (new or recalibrated) with the Immunization Program.

- The current state-supplied data loggers (primaries and backups) will be given to providers free of charge.

2. What must providers do to prepare for this change?

Providers must decide whether to recalibrate existing data loggers or obtain new ones, and must have calibrated, compliant devices in place by October 31, 2018.

3. How do we register our new or recalibrated data loggers?

Use the link below to register your data loggers. Submit a separate report for each of your primary data loggers. Do not register your backup data logger. You will need:

- A digital version of your calibration certificates
- A sample report or data file from each logger like what you would send us in the event of an excursion. We must be able to derive the duration of an excursion and the minimum or maximum temperature achieved from the file or report.

[Data Logger Registry](#)

4. What is not changing?

- Providers are still required to use [VFC-compliant data loggers](#) in their public vaccine storage units and have one backup.
- Providers still must report temperature excursions using our online [Vaccine Incident Report](#).
- Providers still must perform and document [twice-daily temperature checks](#).
- The Immunization Program will still provide technical support for vaccine storage and handling issues but may be limited in helping with data loggers depending on what data loggers are used.

5. What happens between now and October 31, 2018?

- The Immunization Program will continue to support our current data logger program with technical support, batteries, replacements, and data loggers for newly enrolling providers (while supplies last).
- Providers must decide whether to recalibrate existing data loggers or obtain new ones, and must have calibrated, compliant devices in place by October 31, 2018.
- Providers should check the calibration due date on the back of each data logger to determine when the calibration expires.

6. What are the requirements of a VFC-compliant data logger?

Data loggers (primary and backup) must:

- Be continuous recording devices that take readings at least every 30 minutes
- Read temperatures from a buffered probe
- Display the current, minimum, and maximum temperatures on the outside of the storage unit (exceptions for [organization-wide monitoring systems](#))
- Generate data that is reviewable, archivable (3 years), and able to be sent to the Immunization Program
- Alarm to indicate temperatures outside [proper vaccine storage temperatures](#)
- Have a [current calibration](#) performed within the last two years and a [certificate](#) to prove it.

7. Are we required to buy a new backup data logger or recalibrate our current backup?

Not at this time. All VFC providers in Montana have a backup data logger that is calibrated through October 31, 2019. You may choose to buy a new backup data logger now, but the one you currently have is good through October 31, 2019. If you purchase a new backup data logger, try to stagger the calibration due date with that of your primary data loggers so they do not all come due for calibration at the same time.

8. Does our backup data logger have to be the same make/model/type as our primary data loggers?

No. It must be [VFC compliant](#), and you must have the expertise, equipment, and software to quickly deploy it when it is needed. It does not need to be the same make/model/type as your primary data loggers.

9. When do the calibrations expire on our state-supplied data loggers?

- Primary data loggers - October 31, 2018*
- Backup data loggers - October 31, 2019
(Your backup data logger can serve as your backup for another year.)

*Please confirm the calibration due date on your data loggers by checking the white sticker on the back of each device. If we sent you a replacement data logger in the last two years, the due date may be further out than indicated above. In that case, you don't need to recalibrate or replace it until just prior to the actual due date.

10. What is involved in calibrating a data logger?

“Calibration” is checking the data logger’s accuracy by comparing its temperature readings to those of a known standard. Calibration testing must adhere to international standards and be documented with a [certificate of calibration](#). Calibration typically involves shipping the device to a calibration lab. Calibrations can also be performed on-site by a calibration service. You will need to deploy your backup data logger or a loaner from the calibration lab while your data logger is being calibrated.

When arranging a calibration, always confirm:

- The price per device including any shipping charges or loaner options
- The [calibration interval](#) they offer (two years, if possible)
- That the [certificate of calibration](#) meets requirements.

11. How often must data loggers be calibrated?

Data loggers in the Montana VFC Program must be calibrated at least every two years. Some calibration labs may specify how long the calibration is valid with a “due date” for the next calibration. This is called the calibration interval. Be sure to clarify the calibration interval with the lab and always try to get a calibration valid for two years.

- If the certificate has a due date less than or equal to two years from the testing date, recalibrate by the due date.
- If the certificate has a due date greater than two years from the testing date, recalibrate within two years of the testing date. We do not allow calibration intervals longer than two years regardless of the due date on the certificate.
- If the certificate does not have a due date, recalibrate within two years of the testing date.

12. How much does it cost to calibrate a data logger and how long does it take?

Calibrations typically cost from \$40 to \$60 per device. There may be additional charges for shipping and for a “loaner” to use while your data logger is being calibrated (if you choose that option).

The calibration process can take from one week to a month depending on the lab. The calibration lab will provide details on the services they offer and instructions on how to ship your data logger.

13. What are the requirements of a certificate of calibration?

To show compliance with international standards, the certificate of calibration must either:

- Indicate the testing was done by an ILAC MRA¹ calibration lab OR
- Include a statement saying the testing followed one of the following standards:
 - ISO IEC 17025
 - ASTM Standard E2877 tolerance Class F
 - NIST traceability
 - Other Immunization Program approved accuracy validation method (Contact us).

Certificates also must include:

- The name of the calibration lab or entity
- Device make/model and unique identifier (e.g., device number, serial number etc.)
- Date of calibration testing
- Confirmation that the device passed testing with an accuracy of $\pm 1^{\circ}\text{F}$ or 0.5°C .
- Optional - [Calibration due date](#). Some calibration labs may include a calibration “due date” indicating how long the calibration is valid (i.e., calibration interval).

Providers are responsible for calibration certificates and must make them available for review during VFC site visits.

14. How do we find a calibration lab?

We recommend contacting the manufacturer or distributor of your data logger. They may offer calibration services or be able to recommend a lab. Another option, is to choose a lab from this [list of accredited calibration labs](#) compiled by the California Immunization Program.

15. Can our internal bioengineering/maintenance/facilities department perform the calibrations?

Yes, as long as they follow international standards and issue a certificate for each data logger with the [required information](#).

16. Can a calibration entity come to our facility to calibrate our data loggers?

Yes, as long as they follow international standards and issue a certificate for each data logger with the [required information](#).

17. Where can we purchase VFC-compliant, calibrated data loggers?

With the policy change, you are free to obtain [compliant devices](#) from a vendor of your choice. There are many options. Below are a few websites to get you started. We are happy to review the specifications of any device you are considering.

¹ International Laboratory Accreditation Cooperative – Mutual Recognition Arrangement

<https://www.dicksondata.com/hospital-and-healthcare/VFC>

<http://www.vfcdataloggers.com/vfc-compliant-loggers/>

<http://www.berlingerusa.com/fridgetag2/>

<https://www.onsetcomp.com/intemp/products/vaccine-loggers-vfc>

<https://www.microdaq.com/applications/vaccine-monitoring.php>

18. Can our organization-wide temperature monitoring system meet VFC requirements?

Possibly. It must meet [all requirements](#). The challenge with organization-wide systems usually revolves around 1) calibration – the probe in each storage unit must have its own current [calibration certificate](#) – and 2) clinic staff performing and documenting [temperature checks](#) and responding to alarms– some systems do not have temperature read-outs or alarms on the actual storage units. In most cases, these obstacles can be overcome. Contact the Immunization Program if you have questions about using your organization-wide monitoring system.

19. What information must be documented during the twice-daily temperature checks?

- Clinic name
- Storage unit being monitored
- Entry date and time
- Initials of person making the entry
- Alarm status
- Minimum, maximum, and current temperature each morning
- Current temperature each evening

Clinics must also keep a trouble-shooting log for each storage unit that includes:

- Date/time of issue
- Description of the issue
- Action taken
- Outcome
- Immunization Program Contact (i.e., Vaccine Incident Report number or contact person)
- Initials of staff making the entry.

20. Do we still have to use Immunization Program paper temperature logs?

No. You can use any method you want to document temperatures and trouble-shooting as long as it captures the [required information](#) (see question above), can be archived for three years, and made available during VFC site visits for review. You are welcome to continue using our paper temperature logs, which meet all requirements.

21. Is there a generic Immunization Program paper temperature log? Our new data loggers do not have red and green lights.

Yes! We updated our paper temperature logs so they now say “alarm status” rather than “Light green?”. Unfortunately, we can’t offer the logs on our website for download. Contact us, and we will email the new version to you.

22. Can the internal thermometer in our storage unit meet VFC requirements?

Possibly. Again, it must meet [all requirements](#). The challenge with built-in thermometers is usually 1) calibration—the devices usually can't be removed and must be calibrated "in place," and 2) downloading, reviewing, and archiving temperature data. This is often not possible with built-in thermometers.

23. What settings should we use with our new data loggers?

Sampling Rate/Recording Interval (How often the device takes a temperature reading):
At least every 30 minutes.

Alarms:

Set alarms to activate 1° (F) or 0.5° (C) outside proper vaccine storage temperatures.

Vaccine storage temperatures:

Refrigerators	36° to 46°F (2° to 8°C)
Freezers	-58° to 5°F (-50° to -15°C)

Alarm thresholds:

Refrigerator	Lower 35°F (1.5°C)	Upper 47°F (8.5°C)
Freezer	Lower -59°F (-59.5°C)	Upper 6°F (5.5°C)

Alarm Delays—Some devices allow you to set a period of time or number of readings out-of-range before activating the alarm. We allow up to 15 minutes on refrigerators and up to 1 hour on freezers.

24. How do we switch from our old data loggers to our new ones?

You can switch to your new data loggers at any time between now and October 31, 2018. We recommend setting up your new data loggers and running them side-by-side with your old loggers for a few days. Once you are familiar with how your new devices operate and are satisfied with their performance, you can decommission your old data loggers. Don't forget to [register your new devices](#).

25. Do we return the old data loggers to the Immunization Program?

No! We do not want the old data loggers back. They are yours to recalibrate and use elsewhere or throw away. The liquid in the probe vials is food-grade glycol and not hazardous. DO NOT throw away your [backup data logger](#). It is calibrated through October 2019.

26. Can an organization with multiple clinics have just one backup data logger for all the clinics?

The CDC currently allows this as long as the backup data logger can reach a clinic, be installed and operational before the next scheduled temperature check. Although allowed, we strongly discourage this practice and encourage all facilities have one backup data logger on site. We reserve the right to revisit this policy in the future.

When considering this option, please take into account:

- The logistics of getting a data logger to an outlying clinic (staff time, drive time, etc.)
- The possibility of needing more than one backup at a time
- That your clinic may have to reimburse any vaccine lost due to improper temperature monitoring.

Remember—your current state-supplied, backup data logger can serve as your backup through October 31, 2019. You don't need to decide on backup data loggers right away.

27. Our new data loggers text/email/call after hours when there is an alarm. Are we required to respond to temperature alarms after hours, when our clinic is closed?

The Montana VFC Program does not require clinics to respond to temperature alarms after hours, when your clinic is closed. We require after-hours temperature issues be reported as soon as possible the next business day.

Please revisit your clinic policies and make sure they accommodate any new alarm features on your data loggers. Plan ahead for that 2AM text from your refrigerator! If your policy requires staff to respond after hours, the instruction page on our online [Vaccine Incident Report](#) has general guidance on how to handle temperature excursions after hours.